EPA REGISTRATION NUMBER 89459-34 – VOL. 2
PA REGISTRATION NUMBER 09439-34 - VOL. 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 2, 2015

Ms. Kristin Hood Central Garden & Pet Company 1501 E. Woodfield Road, Suite 200W Schaumburg, IL 60173

Subject:

Label Notification per PRNs 98-10 and 2007-4 - Updating the label due to

company transfer; updating the Storage and Disposal/Container Handling

language

Product Name: Prentox Pyrethrum Extract Refined Concentrate

EPA Registration Number: 89459-34 Application Date: June 18, 2015 Decision Number: 506176

Dear Ms. Hood:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notices (PRNs) 98-10 and 2007-4 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRNs 98-10 and 2007-4 and finds that the actions requested falls within the scope of PRNs 98-10 and 2007-4.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-notification via PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Julie Chao at (703) 308-8735 or by email at chao.julie@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 03 Invertebrate & Vertebrate Branch 1 Registration Division (7505P)

y Sun Oa for

Office of Pesticide Programs



PYRETHRUM EXTRACT REFINED CONCENTRATE An insecticide concentrate for formulating use

ACTIVE INGREDIENT:

Pyrethrins	50%
OTHER INGREDIENTS*:	5 <u>0%</u>
TOTAL	100%

^{*}Contains Petroleum Distillates

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. 655-754-89459-34

EPA Est. No.

Net Contents:

Lot No.

NOTIFICATION

89459-34

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

7/2/2015

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

	FIRST AID
If swallowed	 Immediately call a Poison Control Center or doctor. Do not induce vomiting unless told to do so by the Poison Control Center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue to rinse eye. Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-222-2222 248-7763 for emergency medical treatment information. You may also contact the National Pesticide Telecommunication Network at 1-800-858-7378 for information including health concerns, medical emergencies or pesticide incidents.

NOTE TO PHYSICIAN: Contains petroleum distillate – vomiting may cause aspiration pneumonia.

User Safety Recommendations:

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration of their formulated products.

Only for formulation into an insecticide for the following uses: Domestic Indoor (household); Domestic Outdoor (perimeters, lawns and ornamental and vegetable gardens);

 ${\tt Commercial/Industrial/Institutional\ Food/Feed\ and\ Non-Food/Feed\ Areas\ (indoor\ and\ outdoor);}$

Treatments of Animals (including livestock and pets) and Terrestrial Food/Feed and Non-Food/Feed; Greenhouse Food and Non-food.

Not for formulation into wettable powder end-use products (EUP), unless the EUP is packagd in water soluble bags.

Not for formulation into granular end-use products.

Formulated pet spray products must not contain more than 0.2% pyrethrins.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: If container is damaged. Stop any leaks by repositioning the container or by patching or otherwise repairing the leaks. Take care to avoid contact with pesticide and wear protective gear. On cleanup of spilled liquids, wear protective equipment as required to prevent contact with the product or its vapors. Cover the spilled areas with generous amounts of absorbent material, such as clay, diatomaceous earth, sand, or sawdust. Sweep the contaminated absorbent onto a shovel and put the sweepings into a salvage drum. Dispose of wastes as below. Do not store, use, pour, or spill near heat or open flame. PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. {For containers 5 gallons or less} Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available or reconditioning, if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. {For containers greater than 5 gallons} Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or reconditioning, if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

PRENTOX® is a- registered trademark of Prentiss Incorporated Wellmark International

Manufactured by-for:

PRENTISS-LLC

2155 West Croft Circle

Spartanburg, SC 29302

Central Garden & Pet Company

1501 East Woodfield Road 200W

Schaumburg, IL 60173



June 18, 2015

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: R. Gebken, PM 10

SUBJECT: NOTIFICATION PER PRN 2007-4/Storage and Disposal/Container Handling

FOR Prentox Pyrethrum Extract Refined Concentrate/EPA REG. NO. 89459-34

Dear Mr. Gebken:

Enclosed is a completed EPA form 8570-1 and 1 copy of revised labeling for the above product plus one clean copy to serve as notification per PRN 2007-4. The added text represents exact wording from the regulations/PR Notice and other minor changes were made to the label, such as changing the registrant from Prentiss to Central Garden & Pet Company due to the transfer of the product. This action is not a PRIA action and does not require any fee.

If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5360. Thank you for your assistance in this matter.

Yours sincerely,

CENTRAL GARDEN & PET COMPANY

Kristin Hood

Regulatory Affairs Specialist

khood@central.com

enclosure

cc: C. Elmi

REGULATORY LABEL DATA SHEET

File Name:

Epa notif sd add rinse 615

Data Sheet Date:

June 2015

Product:

Prentox PYRETHRUM EXTRACT

REFINED CONCENTRATE

EPA Reg #:

89459-34

(was 655-754)

Approved:

Supercedes:

5/9/13

OVERVIEW: Label notification per PRN 2007-4 to revise Storage and Disposal/Container Handling (add rinse DFU). Exact text from PR Notice was used.

Page #	Description of Major Changes
1	Reference statement, deleted "side panel for", only one pg label EPA Reg No: revised to reflect 11/16/14 transfer from Prentiss to Central Garden Pet Company
2	First Aid – revised telephone number to CGP brand number
4	Storage/Disposal: per PRN 2007-4 (exact text), revised Container Handling to include triple rinse DFU
	Revised trademark reference
	Updated registrant name/address to reflect 11/16/14 transfer from Prentiss to Central Garden Pet Company



PROCESSING REQUEST

Description:	/
Material Available	Electronically (see PPLS):
Electronic Label/Letter	Dated
Other:	
Material Sent (see jac	ket):
☐ Stamped Label/Letter □	Dated
Notification Dated	
New CSF(s) Dated	VIterrate 2 11/17/14
Other:	, , , ,
d clipped together, NOT STAPL aterials to staff in the Informat cket is full or only available as	materials in the jacket. It must be well organized ED. Then give the jacket with the coversheet and ion Services Center (ISC) (Room S-4900). If a an image, please file materials in a new jacket and urther information please call 703-605-0716.
Reviewer: 5. Hobge	ocad
Division:	
Phone: 302-8893	Date: January 20,



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 30, 2014

Ms. Kristin Hood Regulatory Affairs Specialist CENTRAL GARDEN & PET COMPANY 1509 E. Woodfield Road Suite 200W Schaumburg, IL 60173

Subject: CSF Notification

Dear Ms. Hood:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 11/17/14 for **EPA Registration 89459-34**. The Registration Division (RD) has conducted a review of the Confidential Statement of Formula (CSF) submitted with this request for applicability under PRN 98-10 and finds that the change(s) requested falls within the scope of PRN 98-10. Therefore, Alternate 2 CSF dated 11/17/14 is acceptable as a 100% repack. A copy of the CSF has been added to the registration file for the subject product.

Please note that the record for this product currently contains the following CSF(s):

Basic CSF dated 10/17/12

Alternate 1 CSF dated 10/17/12 Alternate 2 CSF dated 11/17/14

Any CSFs other than those listed above are superseded/no longer valid.

If you have any questions, please contact me via telephone at 703-308-8893 or e-mail (hobgood.sherada@epa.gov).

Sincerely,

/s/

Sherada D. Hobgood Notifications Review Coordinator Registration Division (7505P) Office of Pesticide Programs

Ple⊾se read instructions on re	everse before complet.	Jrm.		For	n A, ved. OMB	No. 2070-0060. Approval expires 2-2	8-95
⊕ EPA	Environme	United States ental Protection ashington, DC 204	160		Registration Amendment Other		÷r
		Applic	ation for Pesticide	- Section I			
Company/Product Number Central Garden & Pet Con	mpany/89459-34		2. EPA Product R. Gebken	Manager		Proposed Classification	
4. Company/Product (Name) Central Garden & Pet C Refined Concentrate	ompany/Prentox Pyro	ethrum Extract	PM# 10			X None Restricted	t .
5. Name and Address of Appli Central Garden & Pet Co 1501 East Woodfield Ro Schaumburg, IL 60173	ompany ad, Suite 200W	ZIP Code)		duct is similar		FIFRA Section 3(C)(3) mposition and labeling to:	
			Section - II				
Amendment - Explain bel Resubmission in respons Notification - Explain belo Explanation: Use addition Notification of alternate so Email: sspaulding@central	e to Agency letter dated w. inal page(s) if necessary. curce of active ingredie		ection II.)	Final printed la Agency letter "Me Too" App Other - Explai	lication		
-			Section - III				
1. Material This Product Will	be Packaged In:						
Child-Resistant Packaging Yes X No	Unit Packaging Yes X No If "Yes Unit	No. per	Water Soluble Packag Yes No If "Yes Unit Packaging wgt.	No. per	2. Type of Cont X Meta Plast Glass Pape Othe	il tic s	
* Certification must be submitted	Packaging wgt.	Container	Packaging wgt.	Container			-
3. Location of Net Contents In	formation ontainer	4. Size(s) Retail 30 & 55 gal		5. Lo	ocation of Label Dire X On Label On Label Acc	ections companying Product .	
6. Manner in Which Label is A	ffixed to Product	X Paper Stence	glued iled	Other			
	g I I I I I I I I I I I I I I I I I I I		Section - IV	Western C.	to the beautiful and the second	manual resources	_
Contact Point (Complete Name Steven R. Spaulding	items directly below for		ndividual to be contacted Title Sr. Director, Regulator		Т	plication.) elephone No. (Include Area Code) 47-330-5380	
I certify that the sta acknowledge that under applicable to	any knowingly false or mis	Certifica this form and all at sleading statement	tion achments thereto are true s my be punishable by fine	, accurate and co or imprisonment	omplete. I t or both	6. Date Application Received (Stamped)	a o o
2. Signature Sturn R. &	paulol		3. Title Sr. Director, Regulator	y Affairs		0000	
)						

5. Date

November 17, 2014

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

4. Typed Name

Steven R. Spaulding

White - EPA File Copy (original) * * * Tellow - Applicant copy



United States Environmental Protection Agency Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address

Central Garden & Pet Company 1501 East Woodfield Road, Suite 200W

Schaumburg, IL 60173

EPA File Symbol/Registration Number

89459-34

Product Name

Prentox Pyrethrum Extract Refined Concentrate

Date of Confidential Statement of Formula (EPA Form 8570-4)

11/17/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Pyrethrins CAS# 8003-34-7

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).
- (3) Indicate by checking (A) or (B) below which paragraph applies:
- (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement.

 That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) fisted in paragraph (1).

OR

- (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

	Source			
Active Ingredient	Product Name	Regis	stration Number	
vrethrins				
6			* * * * * * *	
			0 0 0	
			0000	
ignature	Name and Title	Date		***
Steven R. Social D.	Sieven Spaulding/ Senior Director of Regulatory Affairs	11/17/2014		****

Product ingredient source information may be entitled to confidential treatment

Copy 2 - Applicant copy



Kristin Hood

Regulatory Affairs Specialist

Central Garden & Pet Company

1501 E. Woodfield Rd Suite 200W Schaumburg, IL 60173

347-330-5360 phone.

khryodálsenfal min

November 17, 2014

Document Processing Desk (NOTIF)
Registration Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN:

Richard Gebken

Product Manager 10

Subject:

NOTIFICATION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT

Prentox Pyrethrum Extract Refined Concentrate; EPA Reg. No. 89459-34

Dear Mr. Gebken,

Enclosed, please find a notification of additional source of active ingredient for the above subject product.

This product is being submitted per PR Notice 98-10. The alternate source of active ingredient is not registered for residential uses; however, Central Garden & Pet Company (and its affiliates) are a member of the ORETF, NDETF, & REJV. We believe the data submitted by these task forces fulfill the data for residential exposure as noted on the source product label and that this notification is consistent with 40 CFR 152.46.

The following materials are enclosed:

- 1) Application for Pesticide Registration Notification
- 2) Formulator's Exemption Statement
- 3) Confidential Statement of Formula
- Letters demonstrating membership in ORETF, NDETF, & REJV.

If you have any questions, please do not hesitate to contact me at (847) 330-5360.

Sincerely,

Regulatory Affairs Specialist

Enclosures

OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE

David R. Johnson, Ph.D.
ORETF Manager
Johnson Management & Consulting, LLC
Tel (660) 395-9590
Fax (660) 395-9593
davejohn@johnsonngt.com

October 16, 2014

U. S. Environmental Protection Agency 2777 South Crystal Drive Arlington, VA 22202

Subject: Use of Outdoor Residential Exposure Task Force data by EPA for Central Garden & Pet Company registrations

To Whom it Concern:

I am writing this letter as Manager of the Outdoor Residential Exposure Task Force (ORETF). The purpose for this letter is to confirm that EPA is authorized to use data submitted by the ORETF to support Central Garden & Pet Company registrations.

I will be pleased to respond to any questions EPA representatives may have regarding the use of ORETF data for Central Garden & Pet Company.

Regards,

David R. Johnson

ORETF Manager on behalf of

Jeffrey D. Burkey, ORETF Administrative Committee Chair



Aerosol - Air Care - Cleaners - Polishes

Automotive Care - Antimicrobial - Pest Management

September 9, 2014

Mr. Steven R. Spaulding Senior Director of Regulatory Affairs Central Garden & Pet 1340 Treat Boulevard, Suite 600 Walnut Creek, CA 94597

Re: NDETF Member in Good Standing

Dear Mr. Spaulding:

This is to certify that Central Garden & Pet ("Central") is a member in good standing of the Non-Dietary Exposure Task Force (NDETF), and, as such, Central and its affiliates have the right to cite and/or rely on all data submitted by the NDETF.

If you have any questions, please do not hesitate to contact me directly at (202) 833-7315.

Sincerely,

Susan Little

Susan E. Sittle

Executive Director, PIR Program

Consumer Specialty Products Association, Inc.



Acrosol - Air Care - Cleaners - Polishes Automotive Care - Antimicrobial - Pest Management

September 10, 2014

Dr. James McFadden Central Life Sciences 1501 East Woodfield Rd, Suite 200 W Schaumburg, IL 60173

Re: REJV Member in Good Standing

Dear Dr. McFadden:

This is to certify that Central Life Sciences is a member in good standing of the Residential Exposure Joint Venture (REJV), company number 74888, and, as such, has the right to cite and/or rely on all data submitted by the REJV for purposes of responding to U.S. EPA's GDCI dated January 12, 2012, for pyrethrins and pyrethroid use and usage information.

If you have any questions, please do not hesitate to contact me directly at (202) 833-7315.

Sincerely,

Susan Little

Swan E. Sittle

Executive Director, PIR Program

Consumer Specialty Products Association, Inc.

1667 K Street NW, Suite 300 | Washington, DC 20006 | www.cspa.org | p.202-872-8110 f.202-223-2636



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

November 16, 2014

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MR. STEVEN R. SPAULDING CENTRAL GARDEN & PET COMPANY 1501 EAST WOODFIELD ROAD, SUITE 200 WEST SCHAUMBURG, IL 60173

Dear Mr. Spaulding:

Subject: Transfer of Pesticide Registrations and Data From Company Number 655 to Company Number 89459

Pursuant to your request in your letter and transfer agreement of June 04, 2014, we have approved the transfer of the following registrations from PRENTISS LLC, company number 655 to CENTRAL GARDEN & PET COMPANY, company number 89459.

The effective date of these changes is the date of this letter.

	Old EPA	New EPA
Registered Products	Reg. No.	Reg. No.
PRENTOX CUBE POWDER	655-3	89459-13
PRENTOX PYRONYL 50-5 OIL CONCENTRATE	655-52	89459-14
PRENTOX CUBE RESINS	655-69	89459-15
PRENTOX 20% PYRETHRUM EXTRACT	655-75	89459-16
PRENTOX PYRONYL 75	655-87	89459-17
PRENTOX PYRONYL 60-6 EMULSIFIABLE		
CONCENTRATE	655-90	89459-18
PRENTOX PIPERONYL BUTOXIDE TECHNICAL	655-113	89459-19
PRENTOX PYRONYL 9 18-30	655-128	89459-20
PRENTOX PYRONYL 6-15-15	655-316	89459-21
PRENTOX PYRETHRUM CRUDE EXTRACT	655-407	89459-22
PRENTOX PRENFISH TOXICANT	655-422	89459-23
PRENTOX PYRONYL OIL CONCENTRATE #525	655-471	89459-24
PRENTOX PYRETHRUM EXTRACT	655-486	89459-25
PRENTOX PYRONYL CROP SPRAY	655-489	89459-26
PRENTOX PYRONYL OIL CONCENTRATE		
OR-3610A	655-501	89459-27

PRENTOX PRENBAY 1% OIL SOLUTION	655-546	89459-28
PRENTOX EMULSIFIABLE SPRAY		
CONCENTRATE #96	655-587	89459-29
PRENTOX FOGGING INSECTICIDE PF	655-643	89459-30
PRENTOX PYRONYL UL-100 CONCENTRATE	655-665	89459-31
PRENTOX ROTENONE FISH TOXICANT POWDER	655-691	89459-32
PRENTOX PBO 8	655-736	89459-33
PRENTOX PYRETHRUM EXTRACT REFINED		
CONCENTRATE	655-754	89459-34
PRENTOX INSECT SPRAY AND FOGGING		
CONCENTRATE #1	655-773	89459-35
PRENTOX 5 LB. MALATHION SPRAY	655-777	89459-36
PRENTOX PERM-X 1E	655-783	89459-37
PRENTOX FOG AND MILL SPRAY	655-784	89459-38
PRENTOX PRENBAY 1.5 EC	655-796	89459-39
PRENTOX PYRONYL 303 EMULSIFIABLE		
CONCENTRATE	655-797	89459-40
PRENTOX EXCITER	655-798	89459-41
PRENTOX PYRONYL 303 CONCENTRATE	655-801	89459-42
BRITTLE EXTRACT OF CUBE ROOT	655-808	89459-43
PRENTOX PERM-X UL 30-30	655-811	89459-44
PERM-X UL 31-66	655-812	89459-45
PRENTOX PERM-X UL 2-2	655-813	89459-46
PERM-X UL 4-4	655-898	89459-47
PRENTOX CFT LEGUMINE FISH TOXICANT	655-899	89459-48
PRENTOX PERM-X AQUA 20-20	655-900	89459-49
PRENTOX PERM-X AQUA 30-30	655-901	89459-50

SLN Number	Old Registrant/ Company Number	New Registrant/ Company Number
IL110002	655	89459
MO100004	655	89459
UT040001	655	89459
UT050003	655	89459

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after

the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee

is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated June 04, 2014 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date CENTRAL GARDEN & PET COMPANY will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Louis Vaughn at (703) 308-8114.

Sincerely,

Steve Robbins, Chief

Information Services Branch

Alter Alling

Information Technology & Resource Management Div. (7504P)

cc: MS. JANELLE KAY

PYXIS REGULATORY CONSULTING, INC., AGENT FOR

PRENTISS LLC

4110 136TH STREET, NW GIG HARBOR, WA 98332

RE: 655 RAD 89459 11 16 2014

Material Sent for Data Extraction

Reg. #655-754
Description: Amended Under Reregistration
Material(s) Sent to Data Extraction Contractors:
New Stamped Label Dated5/9/13
☐ Notification Dated
New CSFs Dated10/17/12
□ Other:
☐ Decision #:411739
☐ Other Action/Comments:
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.
Reviewer: Julie A. Chao
Phone: <u>308-8735</u> Division: <u>RD/IRB</u>
Date: May 9, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

5-9-13

Sharon M. Johnston, Esq. RegGuide 509 Tower Valley Drive Hillsboro, MO 63050

Subject:

Amended Reregistration Label

Product Name: Prentox Pyrethrum Extract Refined Concentrate

EPA Registration Number: 655-754 EPA Decision Numbers: 411739

Dear Ms. Johnston:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Pyrethrins RED, and has concluded that your submission is acceptable.

NOTE: This product is **not** being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated 10-17-2012
- Alternate CSF #1, dated 10-17-2012

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,

Richard J. Gebken Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Eich Kroft for

Enclosures: La

Label stamped "Accepted"

Acute Toxicity Review, dated November 28, 2011 Product Chemistry Reviews, dated October 31, 2012



Manufactured by:

PYRETHRUM EXTRACT REFINED **CONCENTRATE**

An insecticide concentrate for formulating use.

ACTIVE INGR	REDIENT: 50%
OTHER INGREI	DIENTS*:
Contains Petroleu PRENTOX - Reg	gistered Trademark of Prentiss Incorporated
	KEEP OUT OF REACH OF CHILDREN
	CAUTION
	FIRST AID
If swallowed	 Immediately call a Poison Control Center or doctor. Do not induce vomiting unless told to do so by the Poison Control Center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue to rinse eye. Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.
for emergency m information inclu	container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-222-1222 edical treatment information. You may also contact the National Pesticide Telecommunication Network at 1-800-858-7378 for iding health concerns, medical emergencies or pesticide incidents.
NOTE TO PHY	SICIAN: Contains petroleum distillate – vomiting may cause aspiration pneumonia. SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE
EPA Reg. No. 655	i-754 EPA Est. No.

EPA Reg. No. 655-754	EPA Est. No.
NET CONTENTS	LOT NO

PRENTISS LLC 2155 West Croft Circle Spartanburg, SC 29302

ACCEPTED S-9-13 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No:_

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

User Safety Recommendations:

- · User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- · User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wash-waters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration of their formulated products.

Only for formulation into an insecticide for the following uses: Domestic Indoor (household); Domestic Outdoor (perimeters, lawns & ornamental and vegetable gardens); Commercial/Industrial/Institutional Food/Feed & Non-Food/Feed Areas (indoor & outdoor); Treatments of Animals (including livestock & pets) and Terrestrial Food/Feed and Non-Food/Feed; Aquatic Non-Food; Greenhouse Food & Non-Food.

Nor for formulation into wettable powder end-use products (EUP), unless the EUP is packaged in water soluble bags.

Not for formulation into granular end-use products.

Formulated pet spray products must not contain more than 0.2% pyrethrins.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: If container is damaged: Stop any leaks by repositioning the container or by patching or otherwise repairing the leaks. Take care to avoid contact with pesticide and wear protective gear. On cleanup of spilled liquids, wear protective equipment as required to prevent contact with the product or its vapors. Cover the spilled areas with generous amounts of absorbent material, such as clay, diatomaceous earth, sand, or sawdust. Sweep the contaminated absorbent on to a shovel and put the sweepings into a salvage drum. Dispose of waste as below. Do not store, use, pour, or spill near heat or open flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then, offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Chao, Julie

From:

Personal privacy information

Sent:

Friday, May 03, 2013 12:59 PM

To:

Chao, Julie

Subject: Attachments: Re: 655-75 and 655-754: Reregistration Label Comments 655-75 label 05-03-2013.doc; 655-754 label 05-03-2013.doc

Julie,

Attached are the revised labels for 655-75 and 655-754.

Please let me know if you have any additional changes or comments.

Have a great weekend!

Sharon Johnston RegGuide

In a message dated 4/22/2013 8:01:00 A.M. Central Daylight Time, Chao.Julie@epa.gov writes:

Hi Sharon,

Hope this message finds you well.

Attached are the Agency's comments on the 8-month responses for 655-75 and 655-754. Let me know if you have any questions. Otherwise, you can email me the revised labels.

Thanks, Julie

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 22, 2013

SENT VIA EMAIL

Prentiss LLC c/o Sharon M. Johnston, Esq. RegGuide 509 Tower Valley Drive Hillsboro, MO 63050

Subject:

Request for Updated Reregistration Label for EPA Reg. No. 655-754

Product Name: Prentox Pyrethrum Extract Refined Concentrate

Dear Ms. Johnston,

The Agency has completed a preliminary review of the label that you submitted on behalf of Prentiss LLC in support of the reregistration of EPA Reg. No. 655-754 (Prentox Pyrethrum Extract Refined Concentrate), and has determined that the referenced label did not effectively incorporate all mandatory mitigation language required by the RED for products containing pyrethrins.

Within 10 working days of the date of this letter, you must submit an updated label incorporating the following mandatory mitigation language:

1. Reorder the First Aid statements as follows:

IF SWALLOWED
IF IN EYES
IF ON SKIN OR CLOTHING

The First Aid statements for "If Inhaled" are optional.

The Hazards to Humans and Domestic Animals must be revised to read: "CAUTION.
Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

3. Add the following text to the label:

USER SAFETY RECOMMENDATIONS

- User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside.
 Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.
- 4. Under the Directions for Use, delete the phrase "eligible for re-registration" so the statement for pet products reads, "Formulated pet spray products must not contain more than 0.2% pyrethrins."
- 5. Revise the "Storage" heading to read, "Pesticide Storage." Revise the "Container Disposal" heading to read, "Container Handling."

If we do not receive an amended label in response to this letter, the Agency may pursue further regulatory action, including cancellation under section 6 of FIFRA. If you have any questions about this letter, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,

/s/ Julie A. Chao, for

Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7504P)

DATA PACKAGE BEAN SHEET

Date: 08-Mar-2013
Page 1 of 1

Decision #: 411739

DP #: (409803)

NON PRIA

Parent DP #:

Submission #: 881580

E-Sub #:

* * * Registration Information * * *

655 - PRENTISS LLC		
RM 10 - Richard Gebken - (703)	305-6701 Room# PY1 S-7237	
Moana Appleyard MAPPLEYA		565
07-Sep-2010	PRIA Due Date: 01-Sep-2010	Edited Due Date:
Product Registration - Section 3		
(676) Product Reregistration Dec	sision;	
069001, Pyrethrins (NO INERT I	USE)(50%)	
* * * Data	Package Information *	* *
Yes No	Date Sent: 08-Mar-2013	Due Back:
9	ISE)	
Yes ■ No 069001, Pyrethrins (NO INERT U		
069001, Pyrethrins (NO INERT L	ISE)	
069001, Pyrethrins (NO INERT L	USE)	
069001, Pyrethrins (NO INERT L	USE)	
069001, Pyrethrins (NO INERT Label Inc. 1069001, Pyrethrins (NO INERT Label Inc. 1069001, Pyrethrins (NO INERT Label Inc.) 1069001, Pyrethrins (NO INERT Label Inc.)	USE) cluded: ○ Yes ● No Paren Date In Date Out	
069001, Pyrethrins (NO INERT L	USE) cluded: ○ Yes ● No Paren Date In Date Out	nt DP #:
069001, Pyrethrins (NO INERT Language of the final reregistration for 655-754 ✓ Yes ✓ No Label Inc.	USE) cluded:	nt DP #: Last Possible Science Due Date:
	655 - PRENTISS LLC RM 10 - Richard Gebken - (703) Moana Appleyard MAPPLEYA 07-Sep-2010 Product Registration - Section 3 (676) Product Reregistration Dec	RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237 Moana Appleyard MAPPLEYA 07-Sep-2010 PRIA Due Date: 01-Sep-2010 Product Registration - Section 3

No Studies

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

No Efficacy uses claimed, No Companion Animal uses claimed

This pyrethrins product is recommended for final reregistration based on your review of the attached preliminary label assessment, the 40 CFR and the Pyrethrins RED. Pyrethrins products also have streamlined packages attached, which rely on the same data. In addition, efficacy and companion animal data were called in for all pyrethrins products. This product claimed no efficacy uses or companion animal uses on the label. Please contact Moana Appleyard with questions.

Date: January 16, 2013

Reg. No.: 655-754

Product Name: Pyrethrum Extract Refined Concentrate

[OPPIN Name: Prentox Pyrethrum Extract Refined Concentrate]

PM Name/Number: Richard Gebken/10

Primary Reviewer: Jolene Trujillo Secondary Reviewer: Mark Perry

New label or date of RD amended label: 09/01/10

Formulation Type: Formulation Intermediate

Active Ingredient Assessed: Pyrethrins/069001

Assessment can be found N:\RMIBV\label\000655/754

1) The First Aid statements must be revised to read:

IF SWALLOWED:

Call a poison control center or doctor immediately for treatment advice.

Do not give any liquid to the person.

Do not induce vomiting unless told to by a poison control center or doctor.

Do not give anything by mouth to an unconscious person.

IF IN EYES:

Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

Take off contaminated clothing.

Rinse skin immediately with plenty of water for 15-20 minutes.

Call a poison control center or doctor for treatment advice.

2) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

"CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

3) Per the product chemistry review, the following physical or chemical hazards text must be added to the label:



PYRETHRUM EXTRACT REFINED CONCENTRATE

An insecticide concentrate for formulating use.

ACTIVE INGREDIENT:	
Pyrethrins	50%
OTHER INGREDIENTS*:	<u>50%</u>
TOTAL	100%

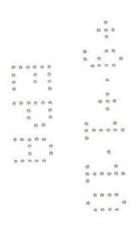
Manufactured by:

PRENTOX* - Registered Trademark of Prentiss Incorporated

	KEEP OUT OF REACH OF CHILDREN
	CAUTION
	FIRST AID
If swallowed	 Immediately call a Poison Control Center or doctor. Do not induce vomiting unless told to do so by the Poison Control Center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue to rinse eye. Call a Poison Control Center or doctor for treatment advice.
If inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.
or emergency monformation inclu	container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-222-1222 dical treatment information. You may also contact the National Pesticide Telecommunication Network at 1-800-858-7378 for ding health concerns, medical emergencies or pesticide incidents.
OTE TO PHY	SICIAN: Contains petroleum distillate – vomiting may cause aspiration pneumonia. SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. 655-754	EPA Est. No.
NET CONTENTS	LOT NO

PRENTISS INCORPORATED 3600 Mansell Road, Suite 350 Alpharetta, GA 30022



^{*}Contains Petroleum Distillates

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Avoid contact with eyes, skin or clothing. Wash hands thoroughly after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wash-waters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration of their formulated products.

Only for formulation into an insecticide for the following uses: Domestic Indoor (household); Domestic Outdoor (perimeters, lawns & ornamental and vegetable gardens); Commercial/Industrial/Institutional Food/Feed & Non-Food/Feed Areas (indoor & outdoor); Treatments of Animals (including livestock & pets) and Terrestrial Food/Feed and Non-Food/Feed; Aquatic Non-Food; Greenhouse Food & Non-Food.

Nor for formulation into wettable powder end-use products (EUP), unless the EUP is packaged in water soluble bags.

Not for formulation into granular end-use products.

Formulated pet spray products eligible for re-registration must not contain more than 0.2% pyrethrins.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: If container is damaged: Stop any leaks by repositioning the container or by patching or otherwise repairing the leaks. Take care to avoid contact with pesticide and wear protective gear. On cleanup of spilled liquids, wear protective equipment as required to prevent contact with the product or its vapors. Cover the spilled areas with generous amounts of absorbent material, such as clay, diatomaceous earth, sand, or sawdust. Sweep the contaminated absorbent on to a shovel and put the sweepings into a salvage drum. Dispose of waste as below. Do not store, use, pour, or spill near heat or open flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then, offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 28, 2011

MEMORANDUM:

Subject:

EPA Reg. No.: 655-754 / Prentox Pyrethrum Extract Refined Concentrate

DP Barcode: 382102 Case No.: 2580

BCH

From:

Bentley C. Gregg, Biologist

Risk Management and Implementation Branch V (7508P)

Pesticide Re-evaluation Division

To:

Moana Appleyard, CRM

Risk Management and Implementation Branch V (7508P)

Pesticide Re-evaluation Division

Applicant:

Prentiss, Inc.

3600 Mansell Road, Suite 350

Alpharetta, GA 30022

FORMULATION FROM EPA Reg. No. 655-754 LABEL:

	% by wt.
Active Ingredient(s):	
Pyrethrins:	50%
Other Ingredient(s):	50%
Total	100%

Contains petroleum distillates

Product ingredient source information may be entitled to confidential treatment

BACKGROUND: In their 8 month response to the Pyrethrins (069001) RED, the registrant has cited some previously submitted acute toxicity studies to support the reregistration of their subject manufacturing-use product, EPA Reg. No. 655-754. The MRIDs cited are 480219-03 (81-1), 480219-05 (81-2), 480219-04 (81-3), 480219-08 (81-4), 480219-07 (81-5), and 480219-06 (81-6). The studies were conducted by Eurofins PSL, with the test material used in each of the studies having been a product deemed herein to be substantially similar to the subject product.

RECOMMENDATIONS:

 The acute toxicity studies cited are acceptable to support the reregistration of EPA Reg. No. 655-754.

The acute toxicity profile for EPA Reg. No. 655-754 is currently:

Acute Oral	III	Cited (LD ₅₀ > 2,000 mg/kg: Up and Down Method: 1/5 died)
Acute Dermal	IV	Cited (LD ₅₀ > 5,000 mg/kg: Deaths: $0/5$ Males; $0/5$ Females)
Acute Inhalation	IV	Cited (LC ₅₀ > 2.02 mg/L: Deaths: 0/5 Males; 0/5 Females)
Primary Eye	III	Cited
Primary Dermal	III	Cited
Skin Sensitization	Sensitizer	Cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 000655-00754

Prentox Pyrethrum Extract Refined Concentrate

SIGNAL WORD:

CAUTION

INGREDIENT STATEMENT:

Contains petroleum distillates.

HAZARDSO TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. *

* The designation of Personal Protective Equipment (PPE) for manufacturing use products does not fall under the jurisdiction of EPA; therefore, PPE has not been specified for this product.

FIRST AID:

IF SWALLOWED: Immediately call a poison control center or doctor. Do not induce vomiting unless told to by a poison control center or doctor. Do not give **any** liquid to the person. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The label must contain the following statement:

NOTE TO PHYSICIAN: Contains petroleum distillates. Vomiting may cause aspiration pneumonia.

DATE OUT: 31/OCT/2012

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP [X]; EUP []

BARCODE NO.: D406139 REG./FILE SYMBOL NO.: 655-754

PRODUCT NAME: Pyrethrum Extract Refined Concentrate

COMPANY NAME: Prentiss, Inc.

ACTION CODE: 676

FROM:

Maria Rivera Piansay, Chemist

Product Chemistry Team

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

TO:

Moana Appleyard, CRM

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

With this resubmission, in response to our review dated 11/10/11, the registrant provided revised Confidential Statements of Formula (CSF) for the basic and the alternate formulation, both dated 10/17/2012, in support the reregistration of their product, EPA Reg. No. 655-754.

FINDINGS:

- 1. EPA Reg. No. 655-754 is a manufacturing-use product, containing the active ingredient, Pyrethrins, with a label claim nominal concentration of 50%. The product is for use in formulating insecticide products. The product is produced by an integrated system. The product is a re-pack.
- 2a. The CSF for the basic formulation (now dated 10/17/2012) had been revised for consistency with the CSF for the "parent" product (boxes 7 and 8 were changed to "7.5-7.9" and >61°C, respectively). The CSF is now acceptable for reregistration of the subject product.

Note that the product chemistry requirements on the source product in the basic CSF have now been satisfied therefore all product chemistry requirements for the subject product are also satisfied.

2b. The CSF for the alternate formulation had also been revised as requested and now shows that the alternate 100% repack source has the same nominal concentration as the subject product. The CSF is now consistent with the product Ingredient statement labeling, meeting PR Notice 91-2. The alternate formulation CSF is now acceptable to support reregistration of this product.

Product ingredient source information may be entitled to confidential treatment

3. The Ingredients Statement on the draft label is acceptable as per CFR §156.10(g) and PR Notices 91-2 and 97-6. The Storage and Disposal Statements are acceptable in accordance with CFR §156.10(i)(2)(ix) and PR Notice 83-3. A Physical or Chemical Hazards subheading and the text "Combustible. Do not use or store near heat or open flame." must be added to the label.

CONCLUSIONS:

The registrant has now satisfied the product chemistry requirements for the reregistration of EPA Reg. No. 655-754.

DATE OUT: 10/NOV/2011

	ECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP [X]; EUP [] CODE NO.: D382101 REG./FILE SYMBOL NO.: 655-754
	OUCT NAME: Pyrethrum Extract Refined Concentrate
	PANY NAME: Prentiss, Inc. ACTION CODE: 676
	15 75 0
FRO	
	Product Chemistry Team
	Risk Management and Implementation Branch V Pesticide Re-evaluation Division (7508P)
	resticide Re-evaluation Division (7508F)
TO:	Moana Appleyard, CRM
	Risk Management and Implementation Branch V
	Pesticide Re-evaluation Division (7508P)
INTR	ODUCTION:
Ingred for cu In the (CSF)	egistration Eligibility Decision (RED), Case No. 2580, was issued on 06/07/2006 for the Active ient Pyrethrins. According to the RED, the generic database supporting the reregistration of Pyrethrins rently registered uses has been reviewed and found to be substantially complete. 8-month response to the Pyrethrins RED, Prentiss, Inc. provided Confidential Statements of Formula for the basic and the alternate formulation, both dated 8/25/2010; a draft label (pin-punched 9/1/10)
	citing product chemistry from to support the reregistration of roduct, EPA Reg. No. 655-754.
FIND	INGS:
1.	EPA Reg. No. 655-754 is a manufacturing-use product, containing the active ingredient, Pyrethrins, with a label claim nominal concentration of 50%. The product is for use in formulating insecticide products. The product is produced by an integrated system. The product is a re-pack.
2a.	The CSF for the basic formulation (dated 8/25/10) indicates that the subject product is a 100% repack of Therefore, the product chemistry data from may
	be used to support the subject product. The data for
	A data gap has been identified in the review. Stability to metals and metal ions (a part of the requirement under GRN 830.6313)
	has not been satisfied. Once the parent product has fulfilled its product chemistry data
	requirements, this repack product will also complete its requirements.

To be consistent with the CSF for the "parent" product, boxes 7 and 8 of the CSF must be changed

to "7.5-7.9" and >61°C, respectively. The CSF is not acceptable at this time.

2b.

- 3. The CSF for the alternate formulation is claimed as a 100% repack of this source has a label claim of active ingredient while the subject product has a label claim of 50%. Therefore, the subject product cannot be repacked from as its alternate source because of the difference in the concentrations. Per PR Notice 91-2, "the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product." The alternate formulation CSF is not acceptable to support reregistration of this product.
- 4. The Ingredients Statement on the draft label is acceptable as per CFR §156.10(g) and PR Notices 91-2 and 97-6. The Storage and Disposal Statements are acceptable in accordance with CFR §156.10(i)(2)(ix) and PR Notice 83-3. A Physical or Chemical Hazards subheading and the text "Combustible. Do not use or store near heat or open flame." must be added to the label.

CONCLUSIONS:

Once the product chemistry data requirements for the parent product are satisfied and after the CSF for the basic formulation is revised, the registrant will satisfy the product chemistry requirements for the reregistration of EPA Reg. No. 655-754.

Product ingredient source information may be entitled to confidential treatment

Personal privacy information



Re: Pyrethrins products for Prentiss

to: Moana Appleyard 10/17/2012 04:17 PM Hide Details

From:

To: Moana Appleyard/DC/USEPA/US@EPA

1 Attachment

PBE

655-754 CSFs 10-17-2012.pdf

Moana,

Corrected CSFs for 655-754 attached. Please let me know if you need anything further.

Sharon Johnston RegGuide

In a message dated 10/17/2012 12:35:22 P.M. Central Daylight Time, Appleyard.Moana@epamail.epa.gov writes:

Hi Sharon,

We are trying to finish up the pyrethrins product reregistration and I have a few Prentiss products that have minor issues:

655-75: Needs revised CSF per review dated July 6, 2011 655-754: Needs revised CSF, boxes 7 and 8 need to match the parent product (7.5-7.9 and >61°C, respectively)

If you could send me the revised CSFs within a week, that would be great.

Thanks, Moana

Product ingredient source information may be entitled to confidential treatment

Re: Need 90 day response for product 655-754

Personal privacy information

to:

Appleyard. Moana 09/13/2010 03:12 PM Show Details

Moana,

There isn't one. This is a 100% Repack of So all that was submitted for this one was the Data Call-In Response form with the listing of all pyrethrins products registered by Prentiss.

Sharon M. Johnston ReaGuide 509 Tower Valley Drive Hillsboro, MO 63050 TEL: 636-942-2583 Cell: 314-520-8554

Fax: 636-948-9720

e-mail: Johnston@RegGuide.net

OR

Personal privacy information

In a message dated 9/13/2010 1:53:54 P.M. Central Daylight Time, Appleyard.Moana@epamail.epa.gov writes:

Hi Sharon.

I am missing the 90 day response for 655-754. Could you email it to me when you get a chance?

Thanks.

Moana

Moana Appleyard Chemical Review Manager Pesticide Re-evaluation Division OPP/PRD/RMIBV (703) 308-8175

appleyard.moana@epa.gov

Pesticide Regulatory Services

RegGuide

August 25, 2010

Document Processing Desk (PRD/DCI)
Pesticide Re-evaluation Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN:

Barbara Briscoe

Chemical Review Manager

Pyrethrins; Case No. 2580; PDCI-069001-26530

SUBJECT:

Pyrethrins - 8-Month Response to Data Call-In Notice

Prentox Pyrethrum Extract Refined Concentrate; EPA Reg. No. 655-754

Dear Ms. Brisco:

Enclosed, please find the 8-month response to the Pyrethrins data call-in notice for the above-subject product.

The following materials are enclosed:

- 1) Application for Registration
- 2) Formulator's Exemption Statement
- 3) Confidential Statement of Formula
- 4) Draft Labeling (5 copies)

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,

Sharon M. Johnston Regulatory Consultant Agent for Prentiss, Inc.

Enclosures

CC.

Larry Eichler; Prentiss

Sharon M. Johnston, Esq. 509 Tower Valley Drive Hillsboro, MO 63050 Tel: 636-942-2583 Fax: 636-948-9720 e-mail: Johnston@RegGuide.net

Please read instructions on r	everse before co.	1 form.		Form Ap	prove	B No. 20	70-0060	D. Approvel expires 2-28-5
\$EPA	Environmental	ited States Protectio gton, DC 204			✓	Registrati Amendme Other		OPP Identifier Number
	Δ.	pplicatio	n for Pesti	ide - Sec	tion	ı		<u> </u>
1. Company/Product Number	655-754		2. EP	A Product Mar Richard		en		pposed Classification
4. Company/Product (Name) Prentox Pyret	hrum Extract Refined	Concentrate	PM#	10				None Restricted
5. Name and Address of App Prentiss, Inc. 3600 Mansell Road, S Alpharetta, GA 30022		(e)	(b)(i), to: EPA	my product	is sim	ilar or identica	l in cor	FIFRA Section 3(c)(3) mposition and labeling
			Section -					
Amendment - Explain Resubmission in responsion in responsion - Explain to the second result of the second results of the second res	palow. al page(s) if necessary. n - 8-month response to	(For section	I and Section II.	Agency let "Me Too" Other - Exp	ter dat Applica	ation.		
			Section -	111				
1. Material This Product Will Child-Resistant Packaging Yes No * Certification must be submitted	Be Packaged In: Unit Packaging Yes ✓ No If "Yes" Unit Packaging wgt.	No. per container	Water Soluble Yes No If "Yes" Package wgt	Packaging No. per containe	r	P	ntainer letal lestic less aper ther (Sp	pecify)
	ntainer	. Size(s) Retai	il Container 5 - 55 gallons		5. Loc	cation of Label (Direction	ns
6. Manner in Which Label is A	Affixed to Product	Lithogra Paper g Stencile	ph lued d	Othe			2/02/04	
			Section -	IV			- ***	
1. Contact Point (Complete it	ems directly below for	identification	of individual to	be contacted,	if nece	ssary, to proce	s this e	application.)
Name Sharon M. Jo	ohnston		itle Agent for Prenti	ss, Inc.		Tel	40 mm	No: (Include Area Code) 6) 942-2583
I certify that the statem I acknowledge that any both under applicable la	knowlingly false or mi	Certificati nis form and a sleading state	l attachments t	nereto are true inishable by fi	o, accu ne or ir	rate and complement or		6. Data Application Received (Stamped)
2. Signature		4	Title Agent for Prer	itiss, Inc.		***	**	
4. Typed Name Sharon M. Johnston			5. Date August 25, 2010					

Sharon M. Johnston

\$EPA

United States

Environmental Protection Agency Washington, DC 20460

-	Fo	rmulator's Exemption S	Statement
Applica	ant's Name and Address	EP	A File Symbol/Registration Number
Prentiss, Inc.			655-754
3600 Mansell Road, Suite 350		Pro	duct Name
Alpharetta, GA 30022			Prentox Pyrethrum Extract Refined Concentrate
			te of Confidential Statement of Formula (EPA Form 8570-4)
			August 25, 2010
As ar	authorized representative of the a	pplicant for registration of the p	roduct identified above, I certify that:
(1)	This product contains the following	ng active ingredient(s):	
	Pyrethrins		
(3)	ingredient in the manufacturing, for which is registered under FIFRA Seach use for which my product is Indicate by checking (A) or (B) be (A) An accurate Confidential State attached to this statement. That finame, the source of the active ing (B) The Confidential Statement of complete, current, and accurate a	ormulation or repackaging anoth section 3, is purchased by us from proposed to be labeled. Now which paragraph applies: The ament of Formula (EPA FORM 85) Tormula statement indicates, by communicate and paragraph (1) OR Formula (CSF) (EPA Form 8570) The amendment of the information required to the contains the cont	-4) referenced above and on file with the EPA is sired on the current CSF.
(4)	The following active ingredients in	Source	nulator's exemption.
	Active Ingredient	Product Name	Registration Number
_			
	Pyrethrins		
	Product ingredient source	l information may be entitled	d to confidential treatment
		I	4.00

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			0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Signa	ture	Name and Title	Date
		Itant August 25, 2010	

EPA Form 8570-27 (Rev. 8-95)

